Remarks/Arguments

The present invention is directed toward a self-expanding stent and stent delivery system for using and treating vascular disease, and in particular to such a system for use in blood vessels within the brain. One of the important aspects of the invention is that the self-expanding stent may be initially positioned at a desired site (note Figure 5) and the stent may be partially expanded at the site. If after the partial expansion of the stent it is determined that the stent is not located in the proper position within the vessel, the stent may be totally withdrawn into a delivery catheter and then may be moved to another location, and then expanded at that location. This feature of the present invention is accomplished by use of anchors that are placed on the strut members and served to interlock in gaps which are formed on the distal end of the core member. This interlocking arrangement between the anchor members placed on the struts members makes possible the partial expansion of the stent while retaining the balance of the stent in a compressed condition within the delivery catheter until the physician has determined that the correct location has been found for the full expansion of the stent.

In order to perform this function, the elongated core member includes a proximal cylindrical member disposed of at a distal portion of the elongated core member and a distal cylindrical member disposed of at the distal portion of the elongated core member. The cylindrical members are spaced apart to define a gap having a predetermined length. The self-expanding stent is comprised of a small diameter skeletal tubular member which includes a plurality of cells and also includes an anchor member placed on one of the strut members and having a link less than the length of the gap between the proximal cylindrical member and the distal cylindrical member. The stent is mounted and compressed onto the elongated core member such as that the anchor member is interlocked within the gap between the cylindrical members to thereby retain the stent on the elongated core member. Actuatable retaining rings retain the self-expanding stent, for upon actuation, releasing the stent to permit the stent to expand. The actuatable retaining rings may take the form of a material, which when heated, yields to permit the self-expanding stent to expand and contact the walls of the vessel. No such structure or function is contemplated by the cited references.

The Rejection

The Examiner has rejected Claims 1 through 5 and 9 "under 35 U.S.C. 103(a) as being unpatentable over Hayashi, et al. in view of U.S. Patent No. 5,919,225 to Lau and in further view of U.S. Patent No. 6,165,213 to Goicochea, et al." Claims 6 through 8 have been rejected "under 35 U.S.C. 103 (a) as being unpatentable over Hayashi in view of Lau and Goicochea, as applied to Claim 5 above, and further in view of Barry."

As indicated, Claims 1 through 5 and 9 have been rejected under a combination of three different patents, i.e., Hayashi, et al., Lau, et al., and Goicochea, et al. Claims 6

through 8 have rejected under a combination of four different patents, i.e., Hayashi, et al, Lau, et al., Goicochea, et al., and Barry. It is clear from the necessity to combine the teaching of in one case three different unrelated patents and in the other case to four unrelated patents that the Examiner has, once having Applicants' invention available to the Examiner, attempted to combine various elements in either three or four unrelated patents in order to "construct" Applicants' device. Even with these combinations of multiple patents there is no suggestion or teaching in any of these patents of placing an anchor member on one of a plurality of strut members which anchor member has a length less than the length of a gap between proximal and distal cylindrical members placed on a core member, and then compressing the device to interlock the anchor member within a tight fitting gap between cylindrical members to retain the stent on the elongated core member.

The Examiner has argued that the radiopaque markers of Hayahi, et al. could serve the function of interlocking with a gap and that the cylindrical members of Lau are "clearly capable of retaining a stent." Applicants agree with these broad statements. The weakness in this argument is, however, that while Lau discloses a gap and the Goicochea reference discloses a radiopaque marker disposed on the struts of a stent, there is no suggestion of placing the radiopaque marker of the Goicochea reference into a gap (a tightly fitting gap) in order to retain the stent onto an elongated core member. Without Applicants' teaching, one of ordinary skill in the art would not think to take the teaching of a radiopaque marker from one reference and a gap (at least ten times the length of the radiopaque marker) on a core member from another reference since the gap in the Lau reference is greater than the entire length of the stent in order to interlock the stent to the core member.

As may be noted by the Lau reference (Figures 19a through 19c) once the stent begins to expand as shown in Figure 19b it would be difficult, if not impossible, to withdraw the stent entirely back into the lumen of the delivery catheter in order to move the stent to a different location. The concept of an interlocking anchor member which is placed on one of the strut members into a tightly fitting gap in order to interlock the stent onto the core member to permit partial expansion of the stent so that the stent may be totally withdrawn back into the delivery catheter is a very important concept of the present invention and is neither taught nor suggested by any of the references. It is not believed that the device "constructed" by the Examiner, to the extent that it is understood how this device would be constructed, would provide this feature which is critically important to the present invention and it is critically important to a physician using a stent and stent delivery system constructed in accordance with the present invention.

More specifically, the references neither teach nor suggest, "an anchor member placed on one of said plurality of strut members and having a length less than the length of the gap between the proximal cylindrical member and the distal cylindrical member, and said self-expanding stent being mounted in compressed onto said elongated core member sets that said anchor member is interlocked within said gap in between said

proximal cylindrical member and said distal cylindrical member to thereby retain said stent on said elongated core member." This language cannot simply be ignored.

Applicants' respectfully traverse the Examiner's rejections of the claims in this patent application for the reason that these rejections rely upon taking various elements, i.e., a radiopaque marker from one reference and a gap (roughly ten times the length of the radiopaque marker) in another reference, along with numerous other features from other references, such as, electrical heated retaining bands, and then combines these with still another reference, showing electrical heating of a resistive heating element, in order to reject the claims of this application. Again, there is no teaching of combining all of these various features of the cited references Clearly it would not be obvious to one of ordinary skills in the art to combine the teachings of these patents. Even if this procedure was proper the gap shown in the Lau reference (Figure 19a) would appear to be at least ten times longer than the radiopaque marker shown in the Goicochea reference. It is not understood how this huge gap would retain the very small radiopaque marker shown by Goicochea.

Accordingly, Claims 1 through 9 clearly define patentable invention over Hayashi, et al., Lau, et al., Goicochea, et al., and Barry taken separately, or in any combination thereof.

Accordingly, a Notice of Allowance is respectfully requested for this application.

In order to preserve the pendency of this application, Applicants will be filing a Request for Continued Examination (RCE) concurrently with the filing of this response. If the Examiner is of the view that an interview might be desirable to resolve any issues in this case, the Examiner is invited to phone Applicant's attorney at the phone number indicated below to discuss these issues.

Respectfully submitted,

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